K113423

MAR - 9 2012

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves - 9.5" Length

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves – 9.5"
Common Name(s):	Powder-Free Nitrile Patient Examination Glove
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);
2. **K101596:** Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Gloves – 12"); Kimberly-Clark PURPLE NITRILE * Powder-Free Exam Glove (Chemotherapy Gloves – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

Device Description(s):

Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves are 9.5-inch long, non-sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets the specifications of ASTM D 6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves - 9.5" Length

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets ASTM Requirements
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	Meets ASTM Requirements

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled): Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves - 12" Length

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves – 12" Length
Common Name(s):	Powder-Free Nitrile Patient Examination Gloves
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Polymer Patient Examination Glove (Product Code LZA)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);
2. **K101596:** Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Gloves (Chemotherapy Gloves – 12"); Kimberly-Clark PURPLE NITRILE * Powder-Free Exam Glove (Chemotherapy Gloves – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves are 12-inch long, non-sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets the specifications of ASTM D 6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application.*

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves - 12" Length

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10	Meets ASTM Requirements
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	Meets ASTM Requirements

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

Section 5 - 510(k) Summary

Preparation Date:	February 14, 2012
Applicant:	Kimberly Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30097
Contact Person:	Lester F. Padilla Tel. No.: 678-352-6766
Trade/Proprietary Name(s):	Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves – 12" Length
Common Name(s):	Powder-Free Nitrile Patient Examination Glove – Tested for Use with Chemotherapy Drugs.
Classification Name:	Patient Examination Glove (21 CFR Part 880.6250), Patient Examination Glove, Specialty (Product Code LZC)

Legally Marketed Device(s) to Which Substantial Equivalence is Claimed:

1. **K102032**: Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Pairs); Kimberly-Clark PURPLE NITRILE* Sterile Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5" Singles); Kimberly-Clark PURPLE NITRILE XTRA* Sterile Powder-Free Exam Gloves (12" Pairs); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Singles);

2. **K101596**: Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (Tested for Use with Chemotherapy Drugs – 12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (Tested for Use with Chemotherapy Drugs – 9.5"); Kimberly-Clark PURPLE NITRILE XTRA* Powder-Free Exam Gloves (12"); Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5");

Device Description(s):

Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves are 12-inch long, non-sterile, purple-colored nitrile, powder-free, ambidextrous patient examination glove that meets the specifications of ASTM D 6319-10, *Standard Specification for Nitrile Examination Gloves for Medical Application*. In addition these gloves were tested for use with the drugs listed in the Intended Use(s) section below, per ASTM D6978-05 *"Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."*

These gloves meet the 2008 Glove Guidance Manual recommended minimum thickness and length specifications for gloves tested for use with chemotherapy drugs.

K113423

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

Intended Use(s):

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15 mg/ml)	Gemcitabine HCl (38.0mg/ml)
Busulfan (6 mg/ml)	Idarubicin HCl (1.0mg/ml)
Carboplatin (10 mg/ml)	Ifosfamide (50.0 mg/ml)
Cisplatin (1.0 mg/ml)	Irinotecan HCl (20.0 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Cytarabine HCl (100 mg/ml)	Melphalan (5 mg/ml)
Dacarbazine (10 mg/ml)	Methotrexate (25 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Mitomycin-C (0.5 mg/ml)
Docetaxel (10.0 mg/ml)	Mitoxantrone (2.0 mg/ml)
Doxorubicin HCl (2.0 mg/ml)	Paclitaxel (6.0 mg/ml)
Epirubicin (Ellence) (2 mg/ml)	Rituximab (10 mg/ml)
Etoposide (20.0 mg/ml)	ThioTEPA (10.0 mg/ml)
Fludarabine (25 mg/ml)	Trisenox (0.1 mg/ml)
Fluorouracil (50.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

Please note that the following drug has low permeation times of less than 60 minutes:
Carmustine (3.3 mg/ml) 30.7 minutes

Summary of Technologies:

The technological characteristics (design, specification, performance) of the Subject Devices and the Predicate Devices are substantially equivalent.

Kimberly-Clark Corporation

Traditional 510(k) Notification (Bundled):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Gloves (12")
Tested for Use with Chemotherapy Drugs

Non-Clinical Testing:

Characteristics	Applicable FDA-Recognized Standards	Performance Results
Dimensions	ASTM D 6319-10 and 2008 FDA Glove Guidance Manual (for thickness and length)	Meets ASTM Requirements and 2008 FDA Glove Guidance Manual (for thickness and length)
Physical Properties	ASTM D 6319-10	Meets ASTM Requirements
Freedom from pinholes	ASTM D 6319-10 ASTM D 5151-06	Meets ASTM Requirements
Powder Free (Powder Content)	ASTM D 6319-10 ASTM D 6124-06	Meets ASTM Requirements
ISO Skin Irritation Study and Sensitization ISO Systemic Toxicity Study	ISO 10993, Part 10 ISO 10993, Part 11	Meets ASTM Requirements
Resistance to Permeation	ASTM D 6978-05 and ASTM F 739-07	Meets ASTM Requirements See Intended Use Section

Clinical Testing:
No Clinical testing was required to determine substantial equivalence of these devices.

Conclusion:
The results of the non-clinical testing demonstrate that the gloves meet the FDA-recognized consensus standards and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kimberly-Clark Corporation
C/O Mr. Ned Devine
Responsible Third Party Official
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, Illinois 60062

MAR - 9 2012

Re: K113423
Trade/Device Name: Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove with Tested for Use with Chemotherapy Drugs Labeling Claim (12" Length)
Kimberly-Clark Purple NITRILE-XTRA* Powder-Free Exam Glove (12" Length)
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Length)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: February 23, 2012
Received: February 24, 2012

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K 11 3423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove With Tested FOR USE WITH CHEMOTHERAPY DRUGS LABELING CLAIM – 12" Length

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

In addition, these chemotherapy gloves were tested for use with the following drug concentrations per ASTM D6978-05:

The following drugs had NO breakthrough detected up to 240 minutes:

Bleomycin sulfate (15 mg/ml)	Gemcitabine HCl (38.0mg/ml)
Busulfan (6 mg/ml)	Idarubicin HCl (1.0mg/ml)
Carboplatin (10 mg/ml)	Ifosfamide (50.0 mg/ml)
Cisplatin (1.0 mg/ml)	Irinotecan HCl (20.0 mg/ml)
Cyclophosphamide (20.0 mg/ml)	Mechlorethamine HCl (1.0 mg/ml)
Cytarabine HCl (100 mg/ml)	Melphalan (5 mg/ml)
Dacarbazine (10 mg/ml)	Methotrexate (25 mg/ml)
Daunorubicin HCl (5.0 mg/ml)	Mitomycin-C (0.5 mg/ml)
Docetaxel (10.0 mg/ml)	Mitoxantrone (2.0 mg/ml)
Doxorubicin HCl (2.0 mg/ml)	Paclitaxel (6.0 mg/ml)
Epirubicin (Ellence) (2 mg/ml)	Rituximab (10 mg/ml)
Etoposide (20.0 mg/ml)	ThioTEPA (10.0 mg/ml)
Fludarabine (25 mg/ml)	Trisenox (0.1 mg/ml)
Fluorouracil (50.0 mg/ml)	Vincristine Sulfate (1.0 mg/ml)

Please note that the following drug has low permeation times of less than 60 minutes: Carmustine (3.3 mg/ml) 30.7 minutes

Elizabeth F. Claxton-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113423

K 113423

Kimberly-Clark Corporation

Indications for Use (cont'd)

510(k) Number (if known): K 113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth A. Claverie-Wilson
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113423

K113423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE-XTRA* Powder-Free Exam Glove (12" Length)

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claxton-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113423

K113423

Kimberly-Clark Corporation

Indications for Use

510(k) Number (if known): K113423

Device Name(s):
Kimberly-Clark PURPLE NITRILE* Powder-Free Exam Glove (9.5" Length)

Indications for Use:
A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth T. Chavis-Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113423